

## **REMARKS**

Claims 1-10 and 12-20 are pending and stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,695,504 to Hanson S. Gifford, III, et al. ("Gifford"). In response to this rejection, the Applicant respectfully submits the following remarks.

### **The Pending Claims and an Example Embodiment**

The Applicant's invention that is the subject of the pending claims is directed to a medical device that includes a clip that can be used, for example, to compress tissue such as at a target ulcer or lesion within a patient's gastrointestinal (GI) tract. The clip is initially coupled to an end of an endoscope, which can be a typical endoscope as is used by GI physicians in viewing the various portions of the GI tract (e.g., esophagus, stomach, intestines, colon). In use of an embodiment of the invention, the clip is coupled to the endoscope and the endoscope is manipulated by the physician such that it is positioned near the wound site. When the target tissue is reached, the clip is deployed from the endoscope, thus compressing the tissue at the wound site to create the desired mechanical compression. In an example procedure, the clip is not intended to be a permanent implant. Instead, it is intended to remain in place until permanent healing is attained, which may be a period of between 48 hours to two weeks. The clip in this example is intended to slough off over time due to the tissue that is compressed within the surgical clip dying from the loss of blood supply to the tissue and/or a slow cutting action applied by the surgical clip itself to the tissue. After sloughing off, the surgical clip is passed as part of the patient's normal digestion. (See specification, paras. 128-132).

The present claims include five independent claims – claims 1, 2, 7, 10 and 15. Each of these claims recites a device adapted to be used with tissue, the device comprising: "an endoscope having a distal end," and "a clip, the clip coupled to the endoscope," the clip comprising: "a ring" or "ring portion;" "a plurality of legs" attached to the ring or ring portion, with "each of the legs being movable between an open position and a closed position to compress [the body] tissue;" and "a locking mechanism to restrict movement of each of the legs from the closed to the open position."

An example of Applicant's invention is illustrated in FIGS. 54 and 59, reproduced below:

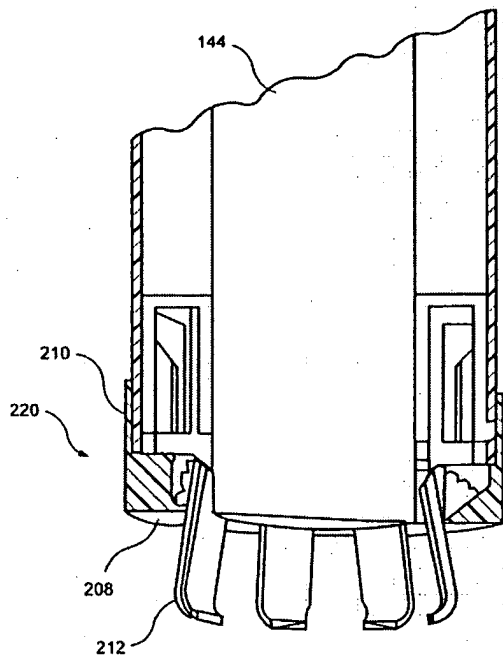


FIG. 54

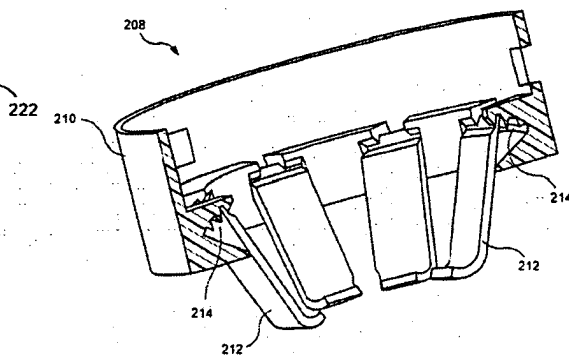


FIG. 49

These figures illustrate an exemplary embodiment of a clip 208 and associated delivery device 220 mounted on an endoscope 144. In this illustrated example, the clip 208 includes a ring portion 210 and multiple legs 212. The ring portion 210 can fit around the outer diameter of the endoscope 144, and the clip 208 can be deployed from the endoscope 144 at the target tissue site. Before deployment, the legs 212 are in an open position. During deployment, the legs 212 are moved to a closed position to compress the tissue. A locking mechanism, which in this example is ratcheting mechanism 214, can be used to control the position of the legs 212 relative to ring portion 210. The ratcheting mechanism 214 can allow legs 212 to move freely from the open to the closed position, but not in the opposite direction. (Specification, para. 176).

### **The Gifford Reference**

The Applicant respectfully submits that the claimed invention is not anticipated by Gifford. Gifford is directed to an “anastomosis” device that can be used, for example, for joining a bypass graft to a patient’s artery.

An example of the Gifford device is illustrated in Gifford’s Figure 1. That device 100 consists of two parts: an anchor member 101, and a coupling member 102. The anchor member 101 is designed to attach to the exterior surface of the wall of a target vessel such as the aorta. The coupling member 102 is designed to attachment to the bypass graft vessel. The anastomosis is formed by joining the coupling member 102 to the anchor member 101, as shown by the dotted lines 103. (Gifford, col. 1, lines 23-32).

Gifford discloses deploying the device using an instrument 118 as shown in Gifford’s Figure 2. The instrument 118 consists of a stapling mechanism 119, a punch mechanism 120, and a graft insertion tool 121, 122. (Gifford, col. 16, lines 33-48).

Gifford illustrates an anastomosis procedure in Figures 5A-5G. A scalpel or other sharp instrument is used to make a slit 150 in the target vessel wall 150. The anvil 136 of the vessel punch 120 is inserted through the slit 151. The stapling mechanism 119 is advanced over the vessel punch mechanism 120 and staples the anchor member 101 to the target vessel wall 150 by its attachment legs 105. Then, the punch mechanism 120 cuts an opening 152 in the target vessel wall 150. The graft vessel insertion tool 121 is then used to press coupling member 102 into the ring-shaped frame 104 of the anchor member 101. In this manner an anastomosis is created. (Gifford, col. 18, line 21 – col. 19, line 58).

The Applicant respectfully points out that the medical procedure conducted in Gifford is a procedure that is entirely different from the procedures for which Applicant’s claimed invention is used. Stemming from these differences, there are a number of differences between the Applicant’s claims and Gifford. For example, the Gifford “instrument 118” is not an endoscope. Accordingly, the Applicant respectfully submits that Gifford does not disclose at least the following elements recited in each of claims 1, 2, 7, 10 and 15 – “an endoscope having a distal end” and a clip “coupled to the endoscope.” Also, due to the stapling, punching, and graft insertion operations performed by Gifford’s instrument 118, it would not be possible or desirable to modify instrument 118 of Gifford to be an endoscope, because that would destroy the

operability of the Gifford mechanism. Moreover, the Office Action does not point to any specific part of Gifford, other than to point generally to “figures 1-56.” It is therefore unclear what the Examiner considers corresponds to Applicant’s claimed “locking mechanism to restrict movement of each of the legs from the closed to the open position.” With respect to the device shown in Figure 1 of Gifford, the legs 105 of the Gifford anchor member 101 as shown in Figure 1 are simply deformed like a staple, and the device does not include any “locking mechanism to restrict movement of each of the legs from the closed to the open position” as recited by the Applicant. For at least these reasons, all of the independent claims, and the claims that depend therefrom, are patentable over Gifford.

Without limitation, and by way of example only, the following additional features are not met by Gifford – “wherein the locking mechanism is a ratchet mechanism” (claim 2), “wherein the ratchet mechanism comprises a plurality of snaps formed on one of the legs and the ring portion” (claim 3), “wherein the locking mechanism is in physical communication with the ring portion at least when the legs are in an open position” (claim 4), “wherein the hinge is a pin and slot hinge, the pin extending from one of the ring portion and each of the legs” (claim 6), “a catch to mechanically retain the legs in the open position” (claim 7), “wherein the hinge is a four bar mechanism” (claim 8), “resilient devices adapted to urge the legs in one of the open and closed positions” (claim 9), “wherein the actuator mechanism comprises strings pulling each of the legs in the closed position” (claim 10), “an actuator mechanism including a rack and pinion arrangement” (claim 12), “an actuator mechanism including a hydraulic piston exerting a force on each of the legs” (claim 13), “a releasable attachment connecting the ring to the endoscope” (claim 15), “wherein the releasable attachment comprises a thread forming a stitch between the ring and the endoscope” (claim 16), “wherein the releasable attachment comprises a seal connecting the ring to the endoscope, and a thread embedded in the seal, such that removal of the thread cuts the seal” (claim 17), “wherein the releasable attachment comprises a protrusion extending from one of the ring and the endoscope and a complementary groove formed in the other of the ring and the endoscope, wherein the protrusion and the groove are connected frictionally” (claim 18), “wherein the releasable attachment comprises a catch extending from one of the ring and the endoscope, a complementary slot formed in the other of the ring and the endoscope, and an actuator for releasing the catch from the groove to release the ring” (claim

19), and “wherein the plurality of legs are releasably attached to the ring” (claim 20). The Applicant thus respectfully submits that these claims are patentable over Gifford for the additional reason that Gifford does not meet these limitations.

### **Conclusion**

For the foregoing reasons, reconsideration of this application and passage to issuance is respectfully requested. The Commissioner is authorized to charge any fees or credit any overpayments which may be incurred in connection with this paper under 37 C.F.R. §§ 1.16 or 1.17 to Deposit Account No. 11-0600.

Respectfully submitted,

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